

Claims

1. A solid oral heparin tablet composition which has a
5 melting point of 25°C or higher, comprising a
continuous lipid component comprising one or more polar
lipids, one or more non-polar lipids, optionally one or
several of water and mono- to trivalent alcohol in an
amount of up to 15% by weight of the composition, and
10 heparin selected from native heparin and fractioned
heparin.
2. The composition of claim 1, substantially consisting
of one or more polar lipids, one or more non-polar
lipids, and heparin.
- 15 3. The composition of claim 1, substantially consisting
of one or more polar lipids, one or more non-polar
lipids, water up to 15% by weight, and heparin.
4. The composition of claim any of claims 1-3, wherein
said one or more polar lipids are membrane lipids.
- 20 5. The composition of claim 4, wherein said one or more
polar lipids are selected from glycolipids.
6. The composition of any of claims 1-5, wherein said
one or more non-polar lipids are glyceride esters of
fatty acids.
- 25 7. The composition of any of claims 1-6, wherein said
one or more non-polar lipids are lipids of vegetable
origin.
8. The composition of claim 7, wherein said one or more
non-polar lipids include triglycerides selected from
30 palmkernel oil fractions obtained by commercial
fractionation of palmkernel oil.
9. The composition of claim 7, wherein said one or more
non-polar lipids include C₈ - C₁₀ monoglycerides and/or
C₁₆ - C₁₈ monoglycerides.

10. The composition of claim 1, comprising water and one or more of mono- to trivalent alcohol.
11. The composition of claim 10, wherein the monovalent alcohol is ethanol.
- 5 12. The composition of claim 11, wherein the divalent to trivalent alcohol is selected from 1,2-propylene glycol, low molecular weight polyethylene glycol, glycerol. The composition of any of claims 1 and 3-13, comprising up to 10% by weight of water.
- 10 13. The composition of claim 12, comprising up to 5% by weight of water.
14. The composition of claim 4, wherein said one or more polar lipids are selected from phospholipids.
- 15 15. A process for the production of an oral heparin tablet which has a melting point of from 25°C and higher, comprising:
- mixing one or several polar lipids with one or several non-polar lipids at a first temperature at which at least one of said components is in a liquid state,
 - 20 - dissolving, in the liquid continuous lipid phase obtained, heparin selected from native heparin and fractionated heparin,
 - cooling the solution of heparin in the lipid phase or portions thereof to a second temperature at which it solidifies,
 - 25 - forming tablets by carrying out the cooling step with aliquots of the solution or from a bulk product obtained in the cooling step.
- 30 16. The process of claim 17, wherein said first temperature is 25°C and higher.
17. The process of claim 15 or 16, wherein said solution is cooled in bulk, comprising forming a powdery product from said bulk product.

18. The process of claim 15 or 16, wherein said solution is fed to a nozzle and sprayed on a surface or into a cavity having a temperature below the melting point of the liquid, thereby forming a powdery product.
- 5 19. A process for the production of an oral heparin tablet comprising compressing the powdery product of claim 17 or 18 into a tablet.
20. The process of claim 19, comprising covering the punch(es) and/or the die for pressing the tablet with an anti-adherent prior to compression.
- 10 21. The process of claim 20, wherein the anti-adherent is selected from stearic acid or a salt thereof.
22. The process of claim 15, wherein the cooling is carried out by pouring an aliquot of said solution into a mould, thereby forming a tablet.
- 15 23. The process of claim 22, wherein the mould is covered with an anti-adherent prior to pouring.
24. The process of claim 23, comprising coating said tablet with one or several powdery pharmaceutical excipients.
- 20 25. The process of claim 24, wherein said one or several excipients are mechanically worked into the surface of the tablet so as to form a coating.
26. An oral heparin tablet essentially consisting of a continuous lipid phase, optionally comprising an inert nucleus, wherein the lipid phase may optionally comprise one or several of water and mono- to trivalent alcohol in an amount of up to 15% by weight of the lipid phase, the composition having a melting point of 25°C or higher and comprising one or more polar lipid components in combination with one or more non-polar lipid components, and heparin selected from native heparin and fractionated heparin.
- 30 27. An oral heparin tablet comprising a core which has a melting point of 25°C or higher, the core consisting of
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- a continuous lipid phase and optionally comprising an inert nucleus, the continuous lipid phase comprising one or several polar lipid components, one or several non-polar lipid components, wherein the lipid phase may optionally comprise one or several of water and mono- to trivalent alcohol in an amount of up to 15% by weight of the lipid phase, and heparin selected from native heparin and fractionated heparin, further comprising a coat consisting of pharmaceutical excipients.
28. The tablet of claim 26 or 27, wherein the coat comprises one or more subcoats consisting of pharmaceutical excipients.
29. A method of treating or preventing a condition amenable to treatment or prevention by administration of a pharmacologically effective dose of heparin, characterized in that the heparin is administered in form of the tablet of claim 26-28.
30. The method of claim 29, wherein said condition is one of deep venous thrombosis, blood clots, pulmonary embolism, unstable angina, atrial fibrillation, acute myocardial infarction, coronary angioplasty, stent placement, coronary artery bypass graft, pulmonary embolism, stroke.